

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

The United States of America ex rel. Scarlett Lutz, Kayla Webster, Dr. Michael Mayes, and Chris Reidel,) C/A No.: 9:14-cv-0230-RMG) (Consolidated with 9:11-cv-1593-RMG) and 9:15-cv-2485-RMG)) Plaintiffs,))) v.))) Berkeley Heartlab, Inc., et al.,))) Defendants.)))

**MEMORANDUM IN SUPPORT OF DENT AND JOHNSON'S RULE 50 AND RULE 59
POST TRIAL MOTIONS**

Defendants Floyd Calhoun Dent, III (“Dent”) and Robert Bradford Johnson (“Johnson”) are entitled to judgment as a matter of law because the government failed to prove key elements of its claims. The government chose to put up only two of its theories of liability: (1) process and handling fees (“P&H Fees”) and (2) the commission structure (“Commission Structure”). The government did not offer evidence that it paid any medically unnecessary claims or engaged in zero balance billing, and it thus effectively abandoned both claims. The proof of the remaining two claims was fatally deficient because the government provided no evidence that P&H Fees constitute “remuneration” or “inducement” under the AKS. Further, the government offered no evidence that P&H Fees or the Commission Structure constituted a “material” violation of a condition of payment under the FCA. Most importantly, the government failed to prove scienter on the part of Dent or Johnson necessary to establish a violation of the AKS or the FCA. In fact, the unwritten law that the government claims the Defendants violated by selling tests for laboratories that paid P&H fees, or by accepting or paying commissions, was not sufficiently

defined such that these Defendants *could* have formed the criminal intent required for them to be held liable in this case. Thus, both remaining theories of liability fail as a matter of law.

The Court has previously addressed some of these legal issues in its pretrial orders. These Defendants respectfully ask the Court to reconsider these issues in light of the full evidentiary record now before it. The Court should find that the government failed to prove essential elements of its claims to the exacting standards required in order to impose punitive liability upon these Defendants.

In the alternative, the Court should grant Dent and Johnson a new trial. The government persisted in making this trial about Dent and Johnson's commercial success and their wealth rather than about their actions. The government successfully opposed Defendants' pretrial motion to preclude evidence of their wealth or the amount of money that they earned. It also prevented the jury from knowing the true extent of its verdict, including trebling and imposition of penalties. Thus armed, the government used the phrase "blood money" twenty-six times over the course of a thirty-seven minute opening statement; once, on average, every one minute and twenty-five seconds. Trial Transcript at 31-55. It referred repeatedly to the total amount of revenue that the Defendants earned (which was not the measure of damages demanded), not the revenue attributable to federal reimbursement. The intent was to inflame the jury against financially successful businessmen, and it worked. The first evening of trial, contrary to this Court's repeated instructions, the jury foreman posted on Facebook: "You get entertained for about 6 hours, by a bunch of people wearing really expensive clothes: Admittedly, I chuckled numerous times...All of that is true, I kid you not[.]" Foreman Facebook Posts (attached as Ex. A). The following day the foreman revealed his disdain for "rich guy[s]": "I don't know why it's so funny when rich people fall down; I can tell you this though, there were at least 100 people, in

that room, who enthusiastically agreed.” Id. (emphasis added). The foreman posted similar posts revealing disdain for guys in “expensive clothes” over the next couple of days. He also specifically noted, by contrast, a government lawyer’s “not at all expensive suit.” Id. The government’s strategy to tar the Defendants with their success led to a miscarriage of justice. The verdict was against the greater weight of the evidence.

Finally, the Defendants are entitled to have the judgment for damages completely offset by the government’s recovery from HDL and Singulex of the same damages that it claimed against these Defendants. Trebling should be based on the net damage award, if any.

For these reasons and those below, Dent and Johnson are entitled to judgment as a matter of law under Rule 50 or, in the alternative, entitled to a new trial under Rule 59.

ARGUMENT

The Court must grant a Rule 50(b) motion for judgment as a matter of law if, “viewing the evidence in a light most favorable to the non-moving party (and in support of the jury’s verdict) and drawing every legitimate inference in that party’s favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party.” Pitrolo v. Cnty. of Buncombe, 407 F. App’x 657, 659 (4th Cir. 2011) (quoting Int’l Ground Transp. v. Mayor & City Council of Ocean City, 475 F.3d 214, 218–19 (4th Cir. 2007)). If reasonable minds could differ, the court must affirm the jury’s verdict. Dennis v. Columbia Colleton Med. Cntr., Inc., 290 F.3d 638, 645 (4th Cir. 2002). Though the movant bears a heavy burden, the “movant is entitled to judgment as a matter of law if the nonmoving party failed to make a showing on an essential element of his case with respect to which he had the burden of proof.” Singer v. Dungan, 45 F.3d 823, 827 (4th Cir. 1995) (internal quotation marks omitted); Bilenky v. Ryobi Techs., Inc., 115 F. Supp. 3d 661, 668 (E.D. Va. 2015).

In the alternative, this Court should grant Dent and Johnson a new trial. Under Rule 59(a), a district court may grant a new trial if: the verdict (1) “is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.” Atlas Food Sys. & Servs., Inc. v. Crain Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996); U.S. ex rel. Drakeford v. Tuomey, 976 F. Supp. 2d 776, 789 (D.S.C. 2013). A new trial is also appropriate to correct an inconsistent verdict. Atlas Food, 99 F.3d at 598. In determining whether to grant a new trial, the court may weigh the evidence and consider witness credibility. Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998); King v. McMillan, 594 F.3d 301, 314 (4th Cir. 2010).

I. There is no evidence of “remuneration.”

An AKS violation requires a defendant to offer or provide “remuneration” to a medical provider to induce a referral. 42 U.S.C. § 1320a-7b(b)(1)(A). “Remuneration” is a necessary element to every AKS claim. Id. This Court properly defined “remuneration” in its jury instruction: “Remuneration includes payment for services already paid by another or payment for more than fair market value.” Trial Transcript (“TT”)¹ at 2949:23-24 (emphasis added). Such definition comports with the statutory definition of remuneration describing it as “transfers of items or services for free or for other than fair market value.” See 42 U.S.C. § 1320a-7a(i)(6).

¹ The trial transcript has now been filed with the Court. For the Court’s convenience, the following page ranges of the transcript can be found at the following docket entries: pages 1 – 237 [ECF #836]; pages 238 – 563 [ECF #837]; pages 564 – 802 [ECF #838]; pages 803 – 1106 [ECF #853]; pages 1107 – 1380 [ECF #854]; pages 1381 – 1667 [ECF #855]; pages 1668 – 1911 [ECF #856]; pages 1912 – 2155 [ECF #857]; pages 2166 – 2426 [ECF #858]; pages 2427 – 2689 [ECF #859]; pages 2690 – 2933 [ECF #860]; pages 2934 – 2980 [ECF #861].

Here, there is no evidence that the P&H Fees² were double-payments.³ The government⁴ agreed that, though 99000 may be reported, it is not payable. TT at 551: 4-9. Moreover, the government witnesses who testified that physicians who reported or billed a claim under CPT 99000 would not expect payment from Medicare: “They understand that there is no additional money to be paid – even they, for accounting, they can put the code on their claim. TT at 549:18-21. Thus, a physician practice⁵ that billed CPT Code 99000 and received P&H Fees did not receive double payment.

² Because the Commission Structure claim also relies on the labs’ payment of P&H Fees to physician practices as evidence of “remuneration,” that claim must fail for the same reasons articulated here.

³ There is no dispute that the P&H Fees here did not exceed fair market value. The government presented no evidence at trial that the P&H Fees were greater than fair market value, and it could not because it did not call its fair market value witness. Rather, the government’s only lay witness to discuss fair market value admitted that the Officer of Inspector General does not make such determinations or provide guidance on methodologies to determine fair market value. TT at 2325:9-18. By choosing not to introduce evidence that any P&H Fee in question exceeded fair market value, it (properly) conceded the point. To the extent the record contains evidence of fair market value, there is no evidence that the P&H Fees exceeded that amount. See TT at 1561-62; BW Ex. 157 (Exponent Study establishing FMV of P&H at \$36); TT at 824:19-25, US Ex. 1253.

⁴ Indeed, no agency of the United States government drafts the CPT codes which are actually created by the American Medical Association (“AMA”) as stated by the United States’ own witness from HHS, “it’s a little bit of an odd system, but Medicare does not actually own the CPT code process.” TT at 531:1-12. Presumably, representatives from the AMA would have been the appropriate parties to address the intent of the coding process, but the United States failed to call any such representatives in this case to explain the meaning, history, or application of CPT 99000. Though there was lay testimony that Medicare and TRICARE reimbursed physician practices for processing and handling specimens through CPT Code 99000, those same witnesses indicated that Medicare and TRICARE reimbursed physician practices \$0 for CPT Code 99000. BW Ex. 511, Medicare Carriers’ Manual Part 3, §5114.1.

⁵ The government’s witnesses’ testimony identified a strange dichotomy that reinforces the testimony that physician practices do not receive double payment through P&H Fees. As the United States’ own witness testified, “whoever draws the blood is responsible for preparing that specimen.” TT at 548:3-4. Furthermore, CMS and Medicare have previously indicated that preparatory services such as preparing a blood specimen for transfer to a lab, “are considered an integral part of the testing process, and the costs of such services are included in the charge for the

Government lay witnesses testified that Medicare and TRICARE reimburse physician practices for processing and handling specimens through the CPT Codes for Evaluation and Management (“E&M”) codes. TT at 548-550; TT at 1076:3-9. While it is true E&M codes are billable and payable, even if it were assumed E&M codes reimburse for processing and handling specimens, there was no testimony or evidence introduced at trial that any physician practice that received P&H Fees was also reimbursed for E&M codes. The importance of this gap in the government’s proof cannot be overstated. There is no evidence in the record related to any claims for physician reimbursement under the E&M Codes and P&H Fees; there is no evidence of Medicare or TRICARE claims data as to physician claims at all. Thus, there can be no evidence in the record specifically identifying physician practices that sought P&H Fees and E&M reimbursements. Because there was no evidence that any physician received double payment through P&H Fees, the P&H Fees cannot be considered “remuneration” under the AKS unless they exceed fair market value.

Further proof that P&H Fees were not double payment arises from the ordering physician’s testimony. Physicians who actually received P&H Fees testified that the fees had no impact on their decision to order the tests and the P&H Fees certainly did not result in a “profit” to them from either “double compensation” resulting from E&M payments or P&H Fees received from HDL or Singulex being above fair market value. For example, Dr. Joseph Hollins

total testing service. “ See BW 511 Medicare Carriers Manual Part 3 – Claims Process Chapter V, Reasonable Charges Section 5114.1 (1992) The Department of Justice conceded this point in a March 18, 2014 letter to BlueWave’s counsel which stated, in part, “By making these payments, the laboratories are essentially sharing a portion of their clinical laboratory fee, providing an incentive for the referring physician to order more tests and increasing the risk of overutilization.” USA Ex. 1497 (attached as Ex. B). Medicare is not expected to pay for the same service twice when billed by two separate providers. If a laboratory relies on a physician to conduct the laboratory’s sample process and handling tasks, it would be improper for that laboratory to retain a Medicare-paid fee for services that it did not actually provide.

testified that: “Whether we receive a process or handing fee has no role in whether I decide to order a lab test” and he continued to order tests after P&H Fees stopped. TT at 2295:5 – 22. Similarly, Dr. Taqueer Alam testified that a \$3 draw fee and a \$17 process and handling fee would not cover his actual costs of processing and handling specimens. TT at 2204:21 – 2205:16. No physician ever testified to any knowledge regarding “double compensation” through the E&M Code and CPT 99000 because such an idea was never contemplated by either the BlueWave defendants or the physicians that ordered the tests.

Two final facts further exonerate Dent and Johnson from responsibility for any double-billing by physicians. First, the process and handling agreements that both HDL and Singulex had with their physician customers all provided that the physician could not both receive P&H Fees and receive reimbursement from any other party. TT at 1512-13, 2467-688 (discussing USA Ex. 2626, ¶ 6 and USA Ex. 1052, ¶ E). Second, neither the laboratories nor Dent or Johnson were, or could be, privy to the physicians’ billing practices. They, like CMS, necessarily relied upon physicians’ compliance with their contractual undertakings to ensure there was no over-reimbursement for services rendered.

For these reasons this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, the jury’s verdict finding is against the clear weight of the evidence.

II. There can be no AKS violation based on the evidence at trial.

A. Dent and Johnson did not, and could not, have the necessary scienter for an AKS violation.

The FCA imposes draconian liability, including treble damages and harsh penalties. The Supreme Court has squarely addressed this fact: “[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,’ concerns about fair notice and open-ended liability ‘can be effectively addressed through strict enforcement of the Act’s materiality and

scienter requirements.’ Those requirements are rigorous.” Universal Health Serv’s, Inc. v. United States ex rel. Escobar, — U.S. —, 136 S.Ct. 1989, ____ (2016), citing United States v. Science Applications Int’l Corp., 626 F. 3d 1257, 1269 (C.D. Cal. 2010) (internal citation omitted).

The scienter requirement for an AKS violation is qualitatively more rigorous than for the FCA standing alone. The AKS is a criminal statute, and it imposes liability only for knowing *and willful* conduct.

Against this backdrop, the evidence unequivocally proves that Dent and Johnson did not have the requisite scienter to be found liable under the FCA, let alone the AKS. Indeed, they could not have had criminal intent because there was no law on the books that criminalized their conduct. The government believes that it establishes liability by showing that the Defendants proceeded in the face of “red flags” that put them on notice that their conduct might be illegal. These red flags comprised various lawyers’ opinions which the Defendants encountered, that differed from the legal opinions upon which they relied. But not a single legal opinion, on either side of the issue, purported to construe the AKS or its regulations. Rather, every opinion was a prognostication of the position that government regulators were likely to take, based upon administrative guidance previously given as to different business practices. These legal opinions consisted entirely of exegesis of a complex array of government administrative interpretations of the AKS and its regulations. The ad hoc administrative legislation that Dent and Johnson are accused of violating is precisely what the Attorney General of the United States decried in his November 16, 2017 memorandum entitled, “Prohibition on Improper Guidance Documents”:

Not every agency action is required to undergo notice-and-comment rulemaking. For example, agencies may use guidance and similar documents to educate regulated parties through plain-language restatements of existing legal requirements or provide non-binding advice on technical issues through examples or practices to guide the application or interpretation of statutes and regulations. But guidance may not be used as a substitute for rulemaking and may not be used

to impose new requirements on entities outside the Executive Branch. Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.

Memo (available at <https://www.justice.gov/opa/press-release/file/1012271/download>).

Similarly, there is no AKS violation in the face of a reasonable interpretation of an ambiguous law because there can be no scienter: “A person who acts, or causes another person to act, on a belief or opinion honestly held is not punishable under the Anti-Kickback Statute merely because the belief or opinion turns out to be inaccurate, incorrect or wrong.” Ameritox, Ltd. v. Millennium Laboratories, Inc., No. 11-775, ECF No. 622 at 18 (M.D. Fl. Jun. 6, 2014). Thus, reasonable interpretation of an ambiguous statute, regulation, or policy guidance, or a reasonable opinion on a disputed legal question, does not constitute a violation of the AKS or the FCA:

[T]he FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations. As this court has recognized, establishing even the loosest standard of knowledge, i.e., acting in reckless disregard of the truth or falsity of the information is difficult when falsity turns on a disputed interpretive question.

U.S. ex rel. Purcell v. MWI Corp., 807 F.3d 281, 287–88 (D.C. Cir. 2015); see United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370 (4th Cir. 2008) (“imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA”); United States v. Prabhu, 442 F. Supp. 2d 1008, 1029 (D. Nev. 2006) (a Defendant does not “knowingly” submit a “false” claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance”). This leads to the more general principle that a party cannot form the necessary scienter for either an AKS or FCA violation based on an ambiguous rule. United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983 (D.C. Cir. 2008); United States ex rel. Oliver v. Parsons Co., 195 F.3d 457, 463–64 (9th Cir. 1999).

Here, the lawfulness of P&H fees was ambiguous as a matter of law, and there is no evidence that BlueWave, Dent, or Johnson's interpretation of the statutory, regulatory, and policy guidance that controlled P&H Fees was unreasonable. As early as 2007, healthcare attorney Greg Root analyzed OIG advisory opinion 05-08, and opined to Berkeley HeartLab ("BHL") compliance officer Jonathan Wolin, also an attorney, regarding BHL's P&H fees as follows:

BHL should continue to structure its specimen collection, processing and handling arrangements so that they comply with the personal services and management safe harbor to federal anti-kickback provisions. 42 CFR 1001.952(d). The safeguards implemented by BHL should allow it to easily comply with this safe harbor. The most crucial requirement of the safe harbor is that compensation is consistent with fair market value...BHL requires any physician practice that enters into an arrangement for the performance of specimen collection, processing and handling to agree to not bill Medicare for specimen collections paid for by BHL. This aspect of the arrangement removes the danger of violating the Civil False Claims Act contemplated in the OIG's advisory opinion.

Mallory Ex. 42 (emphasis added). Dent and Johnson were aware of this legal opinion as a result of their employment at BHL. TT at 1460-70, 2388.

When HDL was first contemplating P&H fees, HDL's healthcare attorney Dennis Ryan reviewed the P&H fee agreements and also approved the May 2010 HDL Position Statement explaining the lawfulness of the P&H fee arrangements. Mallory Ex. 12, 18, 37, 46; USA Ex. 1136. The HDL Position Statement provided, in part, that the HDL "process and handling fee arrangement described above is consistent with the 'arm's length, fixed in advance, fair market value' requirements of the applicable Safe Harbor provisions of the federal Anti-kickback Statute and the Stark Law." USA Ex. 1136 at 2.

Singulex healthcare attorney Mullany reviewed and approved the Singulex P&H fee provisions as well. TT at 2062-64; USA Ex. 1229. Thereafter, in 2012, Ballard Spahr's legal team, including its team manager, Jean Hemphill, along with Ms. Mullany, retained an AKS

expert healthcare compliance specialist company, Navigant, to audit compliance with the AKS. TT at 2087, BW Ex. 150. Navigant reviewed the P&H Fee agreements and the commission agreements for AKS compliance. The audit resulted in a clean report.

On April 27, 2012, LeClair Ryan attorney Ruggio opined that the HDL P&H fees met the safe harbor exceptions under the AKS, which required that the aggregate compensation paid for the services are set in advance and consistent with fair market value, and further opined that the P&H fee arrangements complied with the Civil False Claims Act. Mallory Ex. 7. Even though HDL in-house counsel Kung and outside counsel Hoey eventually came to question the accuracy of the Ruggio opinion with respect to his conclusion regarding compliance with the AKS safe harbor provisions, they never opined that the P&H fees were unlawful and never told HDL or any of the Defendants to stop using P&H fee arrangements until the SFA was issued. TT at 705-6, 828 (Ropes & Gray “never told us to stop paying P&H”); TT at 1294 (Ropes & Gray only talked “about moving away from or phasing out process and handling fees”). In fact, at the June 24, 2013 meeting in Richmond, Virginia, the discussions of P&H fees and what was allowed and not allowed was “confusing” to attorney Linda Flippo. Dent and Johnson were never even informed of Kung’s opinion, and they had only limited and filtered exposure to Ropes & Gray’s opinions.

As noted above, neither the AKS and related regulations nor OIG guidance define fair market value (“FMV”), and no OIG guidance provides standards for determining FMV. TT at 2323-26. The AKS and related regulations do not define commercial reasonableness, and there is no OIG guidance providing standards for determining commercial reasonableness. TT at 2331-33. OIG guidance provides multiple possible definitions of commercial reasonableness, and FMV is considered a “term of art.” TT at 2332. While the government contends that payments

made at FMV do not necessarily mean that they were not intended to induce referrals, TT at 2344-45, the Court's jury instructions provided that "remuneration includes ... payment for more than fair market value." TT at 2949 (emphasis added).⁶ If the Court and the OIG are at odds on the application of FMV payments in the AKS context, then the legality of P&H fees in the context of the AKS, related regulations and guidance must necessarily be deemed ambiguous.

Tellingly, the DOJ did not take a position on the legality of P&H fees as late as January 6, 2014. Mallory Ex. 10 ("DOJ's present refusal to take a position on the straight payment of P&H fees"). The government introduced no statute, regulation, policy, or guidance that unequivocally outlawed P&H Fees; to the contrary, there was evidence that healthcare attorneys believed the 2014 SFA in fact supported the argument in favor of P&H Fees. BlueWave Ex. 123. Even prosecutor Strawn acknowledged the ambiguity and vagueness concerning the practice of P&H fees: "Elizabeth told R&G that they have never had a situation like this in the past where an advisory opinion was written in the middle of an investigation and admitted that these are typically written when there are areas that are vague or not spoken that need to be clarified." Id. (emphasis added). Clearly, the DOJ admitted that the issue as to whether P&H fees potentially violated the AKS was "vague" and needed "to be clarified" by an advisory opinion. The government's admission confirms beyond a doubt the ambiguity in the application of the AKS, related regulations, and OIG guidance with respect to P&H fees.

In the face of such ambiguity, it was unquestionably reasonable for the Defendants to rely on the advice of counsel and continue to promote HDL and Singulex tests, labs that paid P&H

⁶ Even if the government is right that FMV payments can still be an illegal kickback, this would require a subjective determination of intent. This could be done only on a case-by-case basis, since intent would have to be determined from all the circumstances surrounding the payments. The government proffered no evidence that it paid any claim resulting from a P&H payment that was intended to induce the referral.

fees, until the 2014 SFA was issued. Once the SFA was issued, HDL and Singulex stopped paying P&H fees and the Defendants stopped marketing tests associated with P&H fees. Under these circumstances, as a matter of law, the Defendants cannot have had any scienter to violate the law.

The lack of fair warning as to the illegality of Defendants' business practices has constitutional implications. If indeed the AKS is now deemed to outlaw the payment of P&H fees or the payment of sales commissions, then the statute is unconstitutionally vague.

First, the AKS is void as vague as applied to Dent and Johnson. A challenge for vagueness will fail if "reasonable persons" would have known from the language of the statute that "their conduct is at risk." Maynard v. Cartwright, 486 U.S. 356, 361 (1988). A statute can be void for vagueness not only on its face, but as applied, as a result of "unforeseeable and retroactive judicial expansion of narrow and precise statutory language." Bouie v. City of Columbia, 378 U.S. 347, 352 (1964) (emphasis added). "Whether a court is analyzing a statute as void for vagueness on its face or as applied, the essence of the doctrine is that a potential defendant must have some notice or 'fair warning' that the conduct contemplated is forbidden by the criminal law." United States v. Protex Industries, Inc., 874 F.2d 740, 743 (10th Cir. 1989).

The lack of fair warning, here, is apparent by the various, conflicting, and evolving rules, regulations, policies, and non-binding guidance purportedly interpreting the AKS to criminalize P&H Fees or Commission Structures. First, there is no evidence in the record that P&H Fees were ever deemed criminal conduct, even after the June 2014 Special Fraud Alert ("SFA") was issued, until the complaint in intervention in this case was filed. Lawyers drafted and negotiated the initial BlueWave-HDL and BlueWave-Singulex sales agreements which included provisions for P&H fees, commission payments and waivers of copays/deductibles. Mallory Ex. 37, 46

(Attorneys Dennis Ryan and Gene Sellers review of the sales agreements); Mallory Exs. 12, 18 (Attorney Dennis Ryan reviews the HDL 5/1/2010 P&H fee position statement); TT at 2062-64 (testimony of Singulex CEO that health care attorney Mary Mullany of Ballard Spahr reviewed and approved the Singulex-BlueWave sales agreement which included provisions for P&H fees, commission payments, and waivers of copays/deductibles); USA Ex. 1229 (attorneys Sellers and Eddy Kleinhans review Singulex-BlueWave sales agreement). In fact, LeClair Ryan attorney Michael Ruggio opined on April 27, 2012, that HDL's P&H Fees fell into a regulatory safe harbor. Mallory Ex. 7. At no time prior to the SFA did the Defendants' counsel advise that the P&H fees violated the AKS.

Jennifer Williams, a witness testifying on behalf of the government as a representative of the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"), testified that the OIG Advisory Opinion 05-08, which was the government's supposed central guidance regarding its P&H allegations, did not even address or reference P&H fees. TT at 2361. This testimony cannot be overstated; the government admits that this particular guidance did not unequivocally outlaw P&H Fees. Consistent with Williams' testimony, the government would not take an actual position on the legality of P&H fees as late as January 6, 2014. Mallory Ex. 10 ("... HDL is putting further waiver discussions on hold in light of DOJ's present refusal to take a position on the straight payment of P&H fees . . . Leventis noted that he expects DOJ will have to take a position on this issue at some point during the course of the investigation.").

The government introduced no statute, regulation, policy, or guidance that unequivocally outlawed P&H Fees; to the contrary, there was evidence that healthcare attorneys believed the 2014 SFA in fact validated P&H Fees. BlueWave Ex. 123. Even prosecutor and trial counsel Elizabeth Strawn acknowledged the deficiency in the government's notice to health care

providers. Id. . Clearly, by the government's own admission, the general assessment as to whether P&H fees potentially violated the AKS was "vague" and needed "to be clarified" by an advisory opinion, and the Court need look no farther than the government's own acknowledgement to determine that the statute as applied is unconstitutionally void for vagueness.

Further complicating the vagueness related to the AKS, the AKS has no definition FMV, and Williams testified that there is no definition of FMV in the AKS-related regulations and did not identify any such definition in any OIG guidance nor did she identify any standards for determining FMV.⁷ TT at 2323-26. She testified that the OIG merely looks with disfavor towards certain types of remuneration such as per-click, per-order or per-patient payment arrangements. TT at 2326. Williams testified that payments made at FMV do not necessarily mean that there is no inference that the payment was for an inducement of referrals, TT at 2344-45, whereas the Court's jury instructions provided that "remuneration includes ... payment for more than fair market value." TT at 2949 (emphasis added). If the Court and the government's own witness are at odds on the application of FMV payments in the AKS context, then the statute as applied must be considered vague; if the prosecutors cannot determine the rule to be prosecuted, certainly the defendants cannot know their obligation under the law.

⁷ Likewise, the AKS statute has no definition of commercial reasonableness, and Williams testified that there is no definition of commercial reasonableness in the AKS-related regulations and did not identify any such definition in any OIG guidance nor did she identify any standards or methodologies for determining commercial reasonableness. TT at 2331-33. "Q: Is there a definition of commercial reasonableness in any OIG guidance? A: There's not a definition per se, and it's not quite a term of art as fair market value is. You will see it maybe 'commercially reasonable business purpose,' might be 'legitimate business purpose,' might be 'actual and necessary services.'" TT at 2332. Again, if FMV is a "term of art," and there is no definition of commercial reasonableness, the public is not put on fair notice of the requirements of the AKS.

Similarly, there is no evidence of “fair warning” that the Commission Structure used here was criminal conduct. There was no unequivocal evidence that any statute, regulation, policy, or guidance deemed this practice criminal. Government witness Williams testified that the OIG had previously approved of at least two similar commission structure agreements regarding the sale of health care services or items reimbursed by the federal government. TT at 2356 (Williams testimony – OIG issued a favorable opinion (99-3) and would not seek any AKS-related sanctions regarding a sales commission arrangement even though the aggregate compensation took into account the value or volume of the referrals); TT at 2361-63 (Williams testimony – OIG issued a favorable opinion (98-10) and would not seek any AKS-related sanctions regarding a sales commission arrangement for an independent contractor even though the aggregate compensation was not set in advance and took into account the value or volume of the referrals). Williams testified further that there were no definitions of the terms “arranging” or “recommending” in the AKS, AKS-related regulations or OIG guidance, nor any standards in which to determine whether conduct would be considered “arranging” or “recommending.” TT at 2336-40.

As noted above, the Commission Structure arrangement was negotiated and approved by the Defendants’ and the labs’ attorneys. Indeed, none of the Defendants’ business attorneys or healthcare attorneys unequivocally identified the commission structure as criminal, and there is no evidence that the government asserted as much prior to the termination of the respective sales agreements.⁸

⁸ Finally, the AKS alone provides no fair warning from the government that the waiver of copay and deductibles for Tricare beneficiaries was unlawful. There was no unequivocal evidence that any statute, regulation, policy or guidance deemed this practice criminal. As noted above, the waiver of copays and deductibles was a practice negotiated and approved by the Defendants’ and the labs’ attorneys. The only evidence in the record is that the Defendants considered TRICARE

Furthermore, the OIG guidance in the form of the cited advisory opinions, by their own declaration, may not be relied upon by anyone other than the person or entity who requested the opinion. TT at 1364; 42 C.F.R. § 1008.53. Such advisory opinions are not admissible as evidence to prove a violation of the AKS. 42 C.F.R. § 1008.55(b). And, even CMS's Michael Handrigan testified that the OIG's advisory opinions, and specifically the SFA, could not be relied upon as official CMS policy. TT at 543. Simply said, even the government's own 30(b)(6) witnesses testified there was no clear policy on the specific issues here.

In short, there was insufficient warning or notice that these foregoing practices constituted, or may have constituted, criminal conduct in violation of the AKS. Thus, in light of the foregoing related regulations, OIG guidance, and evidence, the AKS is void for vagueness as applied.

B. Independent Contractors

Next, a principal is not responsible for the actions or knowledge of an independent contractor. Patino v. Capital Bonding Corp., 465 F. Supp. 2d 518, 522 (D.S.C. 2006); see Blue Cross & Blue Shield of S.C. v. W.R. Grace & Co., 781 F. Supp. 420, 425 (D.S.C.1991) (holding that an independent contractor was not an agent and any knowledge of the independent

copays and deductibles to be treated similarly to the Medicare program. TT at 1499 (Dent testimony – did not know TRICARE copay or deductible requirements were different from Medicare/Medicaid which prohibits copays or deductibles for lab services); TT at 2417 (Johnson testimony – same). In fact, the government's own TRICARE witness, Alison Coleman, initially and wrongly testified that the TRICARE program requires copays and deductibles from each patient. TT at 1080. She then testified that, in fact, there are many TRICARE programs or plans which do not have copays and deductibles; thus, there are no copays or deductibles to be waived for such plans. TT at 1087. There was no notice TRICARE waivers may be criminal; this renders the AKS as applied here unconstitutionally vague. That the government voluntarily abandoned its claims related to waiver of copays and deductibles, and failed to request any damages or a calculation of the number of claims related thereto, simply underscores the fact that no fair notice regarding the AKS implications for any TRICARE copays and deductibles was ever provided to health care providers.

contractor was not imputed to the principal); see also, e.g., In re Central Gulf Lines, Inc., 176 F.Supp.2d 599, 618 (E.D. La.2001); Gray v. Certain Underwriters of Lloyd's of London, 1999 WL 22844 (E.D. La. Jan.15, 1999). Such rule extends to insulate a principal for the torts of an independent contractor. Mauldin Furniture Galleries, Inc. v. Branch Banking & Tr. Co., No. 10-240, 2012 WL 3680426, at *8 (D.S.C. Aug. 27, 2012) (“any knowledge obtained by an independent contractor is not imputed to the principal or corporation that hired him.”).

Here, there is no evidence that any salesperson was anything other than an independent contractor. The government conceded that all BlueWave sales representatives were independent contractors. [ECF No. 75, ¶¶ 96, 100, 116, 141].⁹ Even assuming their actions were problematic, none of their actions or knowledge can be imputed to Dent or Johnson. It should be noted that, because there was no finding of a conspiracy, it cannot be argued that Johnson, Dent, BlueWave, and BlueWave’s independent contractors are all responsible for each other’s actions as co-conspirators. Because none of the independent contractors’ actions or knowledge can be imputed to Dent or Johnson, there was no finding of a conspiracy, and the government introduced no evidence that Dent or Johnson individually violated the FCA, they are entitled to judgment as a matter of law.

C. Arms Length Sales Commissions are not Kickbacks

Finally, this Court should not construe the AKS to outlaw commission structures. The AKS prohibits the receipt or payment of remuneration for either: (a) referrals of patients for items or services or (b) the purchase of (or arrangement for or recommendation to purchase) a good or service. See 42 U.S.C. § 1320a-7b(b)(1)-(2). A primary purpose of the AKS, in addition

⁹ The record is consistent that BlueWave sales people were independent contractors. TT at 1131:17-21; TT at 2244:4-7; TT at 408:5 – 11; TT at 1825:10 – 14; TT at 1844:3 – 5; TT at 1865:24 – 1866: 1; TT at 1892:7 – 9.

to cost savings, is to prevent the exertion of undue financial influence on physicians that might interfere with the exercise of independent medical judgment:

The Anti-Kickback Statute is designed to prevent Medicare and Medicaid fraud. According to the Health Resources and Services Administration, the Statute was enacted to “protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services.” The Statute has another purpose as well — to protect patients from doctors whose medical judgments might be clouded by improper financial considerations.

See United States v. Patel, 778 F.3d 607, 612 (7th Cir. 2015) (emphasis added) (internal citations omitted); United States v. Dailey, 868 F.3d 322, 331 (5th Cir. 2017), cert. denied, 138 S. Ct. 715 (2018) (“This type of arrangement undermines the purposes of the Anti-Kickback Statute—to prevent fraud and protect patient choice.”); United States v. Onyenso, 615 F. App’x 734, 738 (3d Cir. 2015) (government expert witness “testified that Medicare does not allow the payment of claims tainted by kickbacks because it undermines the basic doctor/patient relationship, incentivizes and encourages overutilization, provides an unfair advantage to providers who accept kickbacks, and increases healthcare costs.”); see McDonnell v. Cardiothoracic & Vascular Surgical Assocs., Inc., No. 03-0079, 2004 WL 3733404, at *9 (S.D. Oh. Aug. 3, 2004). And the rule of lenity applies here and requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them. United States v. Bass, 404 U.S. 336, 347–349 (1971).

Thus, the AKS should not be construed to prohibit Dent and Johnson from receiving legitimate commission payments. BlueWave sales representatives provided marketing materials to physicians stating the benefits of clinical tests offered by HDL and Singulex. BlueWave had entered into commission agreements with those laboratories and was acting—along with its third-party contractors—in conformity with those agreements. Those laboratories would then pay commissions. The government’s claims of misconduct by Dent and Johnson with regard to the commission structure does not implicate the concerns underlying the AKS because the commission structure did not increase costs or, more importantly, unduly influence the professional judgment of physicians. Further, the government presented no evidence that any

physician ordered any HDL or Singulex test based on any consideration other than his or her medical judgment and the testimony showed that only the physicians chose which tests to order regardless of what any sales person might have told them. Dr. Alam TT at 2196:3 – 8; Dr. Hollins TT at 2298:23 – 2299:25; Cornwell TT at 441:23 – 412:3; Carrier TT at 1850:24 – 1851:7 & 1860:12 – 23; Guest TT at 1884:24 – 1885:15; Thomas TT at 1900:18 - 22).

Independently and in support of this argument, this Court should construe the AKS not to outlaw commission structures because such interpretation is unconstitutional. The First Amendment protects truthful and forthright commercial speech, unless there is evidence of false or misleading speech. U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 357, 375-76 (E.D. Pa. 2014) (denying motion to dismiss alleged AKS violation based on the First Amendment solely because the plaintiff had alleged false and misleading speech); see United States v. Mathur, No. 11-312, 2012 WL 4742833, at *11 (D. Nev. Sep. 13, 2012). Restrictions on truthful commercial speech are considered “targeted, content-based” restrictions. Sorrell v. IMS Health, Inc., 564 U.S. 552, 572 (2011). In “the ordinary course it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint discriminatory.” Sorrell, 564 U.S. at 571.

Here, there was no evidence at trial that Dent or Johnson presented false or misleading speech on any sales calls. As such, the government’s interpretation of the AKS criminalizes an independent contractor whose clients provide P&H Fees from giving precisely the same commercial speech as another salesman whose clients do not offer P&H Fees. Because the government has presented no evidence that BlueWave engaged in false or misleading speech, the First Amendment precludes an AKS or FCA violation here. For these reasons, this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, the jury’s verdict finding is against the clear weight of the evidence.

III. There is no evidence of “material” misrepresentations.

The government introduced no evidence that Dent or Johnson’s purported violation of the AKS would have impacted its decision to pay Singulex’s or HDL’s claims. The FCA is “is not an all-purpose antifraud statute[.]” Universal Health Serv’s, Inc. v. United States ex rel. Escobar,

— U.S. —, 136 S.Ct. 1989, 2003 (2016). The FCA only creates liability for violations of “material” conditions of payment. Id. at 2001. And the “materiality standard is demanding.” Id. at 2003. Courts must consider “materiality” in every FCA claim, including FCA claims predicated on an AKS violation. See, e.g., U.S. ex rel. Wood v. Allergan, Inc., — F. Supp. 3d —, 2017 WL 1233991, at *28 (S.D.N.Y. Mar. 31, 2017) (analyzing whether the AKS violation was material); U.S. ex rel. Barko v. Halliburton Co., No. 05-1276, 2017 WL 1018309, at *9 (D.D.C. Mar. 14, 2017); United States ex rel. Brown v. Pfizer, Inc., No. 05-6795, 2017 WL 1344365, at *11 (E.D. Pa. Apr. 12, 2017); U.S. ex rel. O'Donnell v. Am. At Home Healthcare and Nursing Servs., No. 14-1098, 2017 WL 2653070, at *9 (N.D. Ill. June 20, 2017). Though an AKS violation “may be material” under the FCA, it cannot be per se material because materiality requires a case by case analysis. Barko, 2017 WL 1018309, at *9; see United States v. Marder, 208 F. Supp. 3d 1296, 1316 (S.D. Fla. 2016); U.S. ex rel. Hartwig v. Medtronic, Inc., No. 11-413, 2014 WL 1324339, at *12 (S.D. Miss. Mar. 31, 2014); see also 31 U.S.C. § 1320a-7b(g); but see Order [ECF No. 795]. “It is “very strong evidence” that a false statement or AKS violation is not material if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated[.]” Escobar, 193 S.Ct. at 2003-04; see, e.g., City of Chicago v. Purdue Pharma LP, No. 14-4361, 2016 WL 5477522 (N.D. Ill. Sep. 29, 2016); Knudsen v. Sprint Comm's, Co., No. 13-4476, 2016 WL 4548924 (N.D. Cal. Sep. 1, 2016).

Here, there is no evidence that Dent or Johnson made or used, or caused to be made or used, any false statement or record material to a false claim. There is also no evidence that Dent or Johnson presented or caused to be presented any claims with material misrepresentations or material AKS violations. Rather, the evidence in the record shows that only HDL and Singulex and the ordering physicians decided which claims to present to the federal government for payment, and that Dent or Johnson had no input whatsoever in which claims were filed by the

labs.¹⁰ TT at 551-553 (Handrigan testimony – no claims filed for labs by BlueWave, Dent, or Johnson); TT at 2466-67 (Johnson testimony – labs bill government for lab tests); 2102 (Goix testimony – neither Johnson nor Dent caused any false claims to be filed with the government); 2265 (Lively testimony – Johnson and Dent did not conspire to cause false claims to be filed with the federal government). In fact, Mallory testified that Dent and Johnson had absolutely no input in the process of filing claims for reimbursement to Medicare or TRICARE. TT at 825-26. And it cannot be disputed that the government knew about the alleged conduct of these Defendants since at least June 30, 2011, when relator Mayes filed his qui tam lawsuit alleging AKS violations and FCA violations relating to P&H Fees. TT at 478-480, 493, 609-611 (Mayes testimony – filed qui tam suit in 2011 alleging P&H kickbacks); [ECF No. 60 at 2]; TT at 1086, 1092 (Coleman testimony – Tricare representative reviewed the qui tam complaints; Department of Justice came to Tricare with concerns of medical necessity in this case); TT at 704 (Mallory testimony – HDL received DOJ subpoena regarding practice of paying P&H fees in January, 2013); TT at 705 (Mallory testimony – DOJ took a position that P&H fees were illegal in March 2014 but her attorneys told her to not stop paying P&H fees); [ECF No. 91-1].

Contrary to any claim of materiality—let alone claims of per se materiality—the government continued to pay claims to HDL and Singulex through 2014 despite its knowledge of the Defendants’ conduct. TT at 197 (Hines testimony – claims paid through second quarter of 2014). When the federal government pays claims after a suit has been filed alleging that the

¹⁰ Thus, neither Dent nor Johnson were the proximate or efficient cause of any false claims, nor were they a substantial factor relating to any false claim, nor was it objectively or subjectively foreseeable that any of their actions would have caused any false claims to be filed. The physicians and the labs retained complete control over the ordering of lab tests and the claims filing process, which breaks any causal connection of Dent and Johnson to the filing of any false claims or the use of false statements. United States ex rel. DeCesare v. Americare In Home Nursing, 757 F.Supp.2d 573, 589 (E.D. Va. 2010). Further, there is no evidence that link Johnson or Dent to any specific claims filed; no such specific claims were ever identified. The Government failed to prove any causal connection to Johnson and Dent to any false claims on a claim-by-claim basis. United States v. Krizek, 7 F. Supp. 2d 56, 58-59 (D.D.C. 1998); Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 545 U.S. 409, 418 (2005); John T. Boese, Civil False Claims and Qui Tam Actions § 5.08[A][2] (3d ed.).

claims are not lawful and are false, the said claims cannot be material. City of Chicago v. Purdue Pharma LP, No. 14-4361, 2016 WL 5477522 (N.D. Ill. Sep. 29, 2016) (claims are not material if they are paid after suit was filed).

Since there is no evidence that any alleged false claim was materially false as Escobar requires, this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, the jury's verdict finding is against the clear weight of the evidence.

IV. The government's P&H Fees claims fail.

A. Safe Harbor

There can be no AKS violation because the P&H Fees here fall into the regulatory safe-harbor for personal services. That safe harbor requires that any party seeking its protection satisfy seven elements. 42 C.F.R. § 1001.952(d). There is no dispute for six out of seven of the elements. The only disputed element requires the “aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.” 42 C.F.R. § 1001.952(d)(5). The AKS does not define those terms. However, the Stark Law does.

Under the Stark Law's definitions, the P&H agreement fits within safe harbor because the P&H Fee amount is considered set in advance and those amounts do not change regardless of how many tests are ordered.¹¹ Under Stark definitions, 42 C.F.R. § 411.354(d)(1)-(2), this is copacetic. This Court should look to definitions in Stark Law because it uses the same terms, the same agency (HHS) administers it, and it shares a subject matter.

B. The Court should adopt the primary purpose test rather than the government's proposed one purpose test.

¹¹ Likewise, the sales commission agreements would also fit within the safe-harbor for the same reason—the commissions are set in advance and do not change with the number of tests ordered.

The primary purpose of the P&H Fees—in fact their only purpose—was to reimburse physicians, not induce physicians to order tests. The Fourth Circuit has yet to choose between the “one purpose” test and the “primary purpose” test. See U.S. ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 697 (W.D. Ky. 2008) (discussing the different tests). The primary purpose test is best described by the First Circuit in a jury instruction it upheld:

If you find the payments were made for two or more purposes, then the government has to prove that the improper purpose is the primary purpose or was the primary purpose in making and receiving the payments. . . . You cannot convict if you find that the improper purpose was an incidental or minor one in making the payments.

United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 30 (1st Cir. 1989) (adopting the primary purpose test). The primary purpose test gives due respect to lawful acts that fall outside of a safe harbor but are not criminalized by the AKS¹². See Feldstein v. Nash Cmty. Health Servs., Inc., 51 F. Supp. 2d 673, 682 (E.D.N.C. 1999) (recognizing the “failure to fall within a safe harbor, however, does not necessarily mean that the conduct/relationship is prohibited by the anti-kickback statute.”). The one purpose—or more properly termed the “any purpose” test—eliminates this space for extra-safe-harbor, lawful conduct. The AKS is certainly not intended to criminalize all extra-safe-harbor acts.

Here, HDL’s May 2010 Position Statement, drafted by LeClair Ryan attorney Dennis Ryan, described P&H Fees as follows: “The purpose of this document is to provide support and due diligence in consideration of the current practices of providing a fee to physicians to reimburse the costs associated with the extensive processing and handling of samples collected at an independent location for testing [HDL]. This reimbursement is not specific to the costs

¹² This Court gave credence to this principle in its jury instructions. TT at 2249:12-15 (“However, just because the defendants’ conduct or arrangements did not fit into a safe harbor does not mean that their conduct violated the Anti-Kickback Statute.”).

associated with performing venipuncture.” USA Ex. 1136; TT at 1504. As indicated, the purpose of the P&H Fees was to reimburse physicians and/or partner laboratories for the costs associated with the processing and handling of blood test specimens.

There is no testimony or evidence in the record that reasonably indicates that one purpose or any purpose of the P&H Fees was to unlawfully induce referrals of lab tests to HDL or Singulex. Rather, all of the salesman to testify—even those called by the government—noted that the purpose of the P&H Fees was to reimburse, not to induce referrals. TT at 420 (Cornwell testimony); see also TT at 263; TT at 2596 (Johnson testimony); TT at 2255 (Lively testimony); TT at 2114 (Dent testimony). Because no purpose of the P&H Fees paid by HDL or Singulex was to unlawfully induce physician referrals of lab tests, there was no willful or knowing intent to unlawfully violate the AKS or the FCA.

For these reasons, this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, the jury’s verdict finding is against the clear weight of the evidence.

V. The government abandoned its medical necessity and zero balance billing claims.

The government abandoned its medical necessity and zero balance billing claims. Regardless, over the Defendants’ objections, the Court erroneously allowed evidence of waiver of TRICARE co-pays, deductibles, and cost shares even though the government abandoned this claim in its opening statement and its first witness. This was prejudicial to the Defendants, confusing to the jury, and might have well been a basis for the jury’s finding of liability that the Defendants violated either the AKS or FCA. There was no allegation in the Complaint in Intervention that cost shares were illegally waived, yet government witness Coleman testified as to TRICARE cost shares implying that these were illegally waived when they were not even in issue. TT 1079-81; 1084-85. There was no evidence admitted which indicated that any of the

TRICARE beneficiaries for whom tests were ordered had plans which required a copay or deductible to be paid, no damages evidence, and no number of claims. The Government's witness could not even identify all of the TRICARE plans which had no copays or deductibles, and gave confusing testimony on the difference between cost shares, copays, and deductibles. TT at 1085-88. Further, there is no evidence that any of the Defendants knew that waiver of TRICARE copays or deductibles was illegal. TT at 1302, 1511, 1585, 1605, 2563, 2606. Medicare clearly does not require a copay or deductible for lab services. TT at 1083. There is no evidence that any BlueWave representative knew if any patient had a TRICARE plan which required a copay or deductible. There is no evidence that any patient was induced by any waiver of any copay or deductible to have a test ordered for the patient. Thus, the erroneous admission of such irrelevant evidence only served to prejudice and inflame the jury against the Defendants, was a miscarriage of justice, and certainly justifies a new trial. And to the extent it did not, it did not put up any damages for its waiver of copays and deductibles theory; thus, it has failed to show an essential element of this claim.

To the extent this claim survives, the government's first witness, its damages expert, testified that he prepared analyses for only two of the government's theories of liability. TT at 110: 18-21. Mr. Hines explained his damages theory related to process and handling in detail. TT at 112 – 199. But he always limited his damages calculations to those damages associated with P&H Fees and commissions. See, e.g., TT at 153:8-10; 165:11-14. On the government's redirect, it is obvious that Mr. Hines only testified to damages associated with P&H Fees and, arguably, commissions. TT at 226 – 227:3. Because the government introduced no evidence related to the number of claims or damages for its claims related to medical necessity or the waiver of copays and deductibles, this Court should grant Dent and Johnson judgment as a matter of law or, in the

alternative, the jury's verdict finding is against the clear weight of the evidence. Otherwise the number of claims and damages related to medical necessity and waiver of copays and deductibles are purely speculative.

VI. There is no evidence of a medically unnecessary test.

To the extent this claim was not abandoned and survives without proof of damages or number of claims, it cannot survive because no treating physician testified to a single medically unnecessary test. Only a treating physician is responsible for whether a particular test that is ordered is medically necessary: a "laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary." United States ex rel. Groat v. Boston Heart Diagnostics Corp., No. 15-487, 2017 WL 6327540, at *3 (D.D.C. Dec. 11, 2017). Like a lab, a sales force cannot and is not required to determine medical necessity; salesmen are even more attenuated and distant from the actual ordering of tests than a lab. See id.

Here, the government introduced no evidence from treating physicians of any medically unnecessary tests; the government's medical expert did not even review a single patient file. And even if they did, Dent and Johnson cannot be liable for such medically unnecessary tests because they did not influence or exercise the medical judgment to order such tests. The salesforce is in no position to second-guess a physician at the time of ordering the test or at the time of conducting the test. Further, if there is a difference of opinion between two physicians over a particular test for a particular patient, such reasonable disagreement precludes an FCA violation. U.S. ex rel. Purcell v. MWI Corp., 807 F.3d 281, 287–88 (D.C. Cir. 2015). Here, as noted above, Drs. Allam and Hollins all agreed that no medically unnecessary lab tests were ordered. Any

evidence to the contrary is simply a difference of medical judgment or professional opinion, which cannot constitute a false claim.

VII. The government's equitable claims must fail.

The government presented its case and submitted its case to the jury on purely legal grounds; Dent and Johnson are now entitled to judgment as a matter of law on the government's remaining equitable claims. A suit in equity will not lie when there is an adequate remedy at law. See Morales v. Trans World Airlines, Inc., 504 U.S. 374, 381 (1992); Banner Life Ins. Co. v. Noel, 505 F. App'x 250, 254 n.4 (4th Cir. 2013) (quoting Catholic Soc. of Relig. Literary Educ. v. Madison Cnty., 74 F.2d 848, 850 (4th Cir. 1935)). Such limitation is necessary "to prevent erosion of the role of the jury and avoid duplication of legal proceedings and legal sanctions where a single suit would be adequate to protect the rights asserted." Younger v. Harris, 401 U.S. 37, 44 (1971). A legal remedy is adequate—and thereby precludes a duplicative equitable remedy—if it is as complete, practical, and efficient as its equitable analogue. See Terrace v. Thompson, 263 U.S. 197, 214 (1923).

Here, the government has presented no evidence that its FCA claims are not adequate. There can be no dispute that claims for payment by mistake of fact and unjust enrichment are equitable claims. See U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394 (4th Cir. 2012) (identifying claims for payment by mistake of fact and unjust enrichment as equitable claims). But the FCA provides the government with a complete, practical and efficient legal remedy, and it has provided no evidence to the contrary. Thus, this Court should grant BlueWave, Dent, and Johnson judgment as a matter of law on the government's equitable claims.

To the extent these claims survive there is no evidence of any mistake of fact. “A claim for payment by mistake of fact allows the Government to recover funds which its agents have wrongfully, erroneously, or illegally paid.” United States v. Fadul, No. 11-0385, 2013 WL 781614, at *12 (D. Md. Feb. 28, 2013) (quoting United States v. Medica–Rents Co., 285 F. Supp. 2d 742, 776 (N.D. Tex. 2003) (internal quotation marks and citation omitted)). Here, the government introduced no evidence at trial that its agents wrongfully, erroneously, or illegally paid HDL or Singulex claims. The witnesses on behalf of the government, Dr. Handrigan and Allison Coleman, did not testify to a mistake, error, or nefarious payment to HDL or Singulex.

Similarly, the government presented no evidence of any unjust enrichment. The equitable doctrine of unjust enrichment allows recovery of money that should not be retained when there is no controlling contract. In re Chateaugay Corp., 10 F.3d 944 (2d Cir. 1993). The touchstone of an unjust enrichment claim is that the party against whom recovery is sought must have wrongfully received a benefit that would be unconscionable to retain. United States v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 450 (E.D. Pa. 2004). Here, there is a controlling contract; the agreements between HDL and Singulex and Medicare and TRICARE. Those contracts control and, therefore, the government cannot succeed on its unjust enrichment claim. Id. Further, there was no evidence that Medicare or TRICARE reimbursed HDL or Singulex for tests that did not get performed. HDL and Singulex indeed performed every test that it claimed it performed; there is no evidence or testimony to the contrary. Because Medicare and TRICARE received the service they paid for, there can be no claim to unjust enrichment.¹³

¹³ “The Government cannot claim a loss when it reimbursed a Medicare [or TRICARE] provider for services that were actually rendered unless the payment exceeds the value of the services.” U.S. ex rel. Davis v. Dist. of Columbia, 679 F.3d 832, 839 (D.C. Cir. 2012); U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 923 (4th Cir. 2003); United States v. Razalan, 725 F.Supp.2d 636 (E.D.Mich. 2010) (government cannot claim a loss when a

Finally, the government did not mitigate its damages, and unnecessarily and prejudicially delayed bringing its equitable claims and thus acted with unclean hands. As a result, it is not entitled to recover on equitable claims.

VIII. Testimony about Dent's and Johnson's earnings led to miscarriage of justice.

The government's inflammatory use of Dent's and Johnson's earnings (permitted by this Court's motion in limine ruling) led to a miscarriage of justice. Dent and Johnson sought to preclude any evidence of their earnings through a motion in limine. [ECF No. 587]. They argued that their personal earnings were irrelevant because the government calculated damages through CMS's payments to HDL and Singulex, not through Dent's or Johnson's earnings. Id. Dent and Johnson argued that the government's only desire to use their earnings was to "incite jealousy and resentment" against Dent and Johnson. [ECF No. 587 at 10]. The Court rejected the argument, finding Dent and Johnson's earnings relevant to "remuneration" and "motive." [ECF No. 727 at 11].

The government's intent to use Dent and Johnson's earnings for purely inflammatory and improper purposes materialized in its opening statement. The government summarized its theory of the case within the first minute of its opening statement: "this case is about the love of money[;] It's about what the defendants were willing to do for the love of money." TT at 31:19-21. The government characterized its theory with the catch phrase "blood money."¹⁴ TT at 32:11-

defendant was reimbursed for legitimate services even though tainted by kickbacks); United States v. Vaghela, 169 F.3d 729, 736 (11th Cir. 1999). This is the case for both the government's equitable and legal claims under the FCA.

¹⁴ The term "blood money" is commonly understood to describe a financial transaction, bribe, or ransom to cause or prevent physical harm to an individual. See Blood Money, Black's Law Dictionary (10th ed. 2014). Here, the government provided no testimony or evidence that anyone who received a blood test was caused harm. Thus, its use of the term "blood money" was contrary to the common understanding of that term. The repeated use of the phrase "blood money" was so

15 (“their scheme was simple. It was blood money.”). The government used this phrase twenty-six times over the course of its opening statement; government counsel repeated “blood money” once, on average, every one minute and twenty-five seconds. TT at 31-55. The government’s inflammatory misuse of earnings went well beyond this attempt at pith.

The government presented an inflated view of Dent and Johnson’s earnings from tests reimbursed by CMS because the government repeatedly referred to Dent and Johnson’s total earnings, not just earnings from federal health care programs. Hines identified actual damages of \$176,543,901 by reviewing all payments that federal health care programs made to HDL and Singulex. TT at 198:20-23; 2674. The total damages the government sought, therefore, were the payments CMS made to HDL and Singulex. It would stand to reason the government should describe Dent and Johnson’s earnings related to the actual damages to CMS; the commissions Brad and Cal earned on tests reimbursed by CMS. But when Hines described Johnson’s and Dent’s earnings, Hines determined that Dent and Johnson earned \$53.2 and \$52.2 million, respectively, from their commission based on reimbursements from both CMS and private payers. TT at 187:6-13. By describing actual damages in terms of CMS payments and Dent and Johnson’s earnings in terms of CMS and private payments, it improperly presented Dent and Johnson’s earnings as more than 50% of the actual damages. This unbalanced, inflammatory description of Dent and Johnson’s earnings compared to actual damages continued through the closing statement. TT at 2647. And this misleading equivalency on the first day of trial had a demonstrable, improper impact on the jury.

inflammatory and prejudicial that it alone should be the basis of a new trial. See Toyota of Florence, Inc. v. Beasley, 314 S.C. 257 (1994).

That evening, on January 16, 2018, the jury foreman described the first day of trial on Facebook: “You get entertained for about 6 hours, by a bunch of people wearing really expensive clothes: Admittedly, I chuckled numerous times...All of that is true, I kid you not[.]” Foreman Facebook Posts (emphasis added). Of course, this post violated the Court’s clear instructions. TT at 29:3-8. The foreman’s comments related to wealth and expensive clothing continued.

The following day the foreman revealed enjoyment watching “rich people fall down:”

Anyway, while we were in the big room, run by a nice little old guy in a black dress, we had one of those days. You know, the kind that makes you want to go back tomorrow. The 12 of us literally laughed out loud 3 times. That includes the time when a really rich guy in expensive clothes, showed us his best Chevy Chase impression and did a faceplant right in front right in front of the “dress” guy’s desk. I don’t know why it’s so funny when rich people fall down; I can tell you this though, there were at least 100 people, in that room, who enthusiastically agreed. Tomorrow I’ll fill you in on our “one glass of wine limit” lunch and our cutthroat Uno tournament, unless some other funny stuff happens.

Id. (emphasis added). The next day, on January 18, 2018, the foreman again commented directly on apparent wealth: “A guy in really expensive clothes, asked a guy sitting in a wooden box, if he recognized him from the last time they met.” Id. (emphasis added). Finally, in his last public post¹⁵ on the trial, the foreman’s distaste for wealth continued:

Unfortunately I can only tell you one because the rest fall under that non-disclosure thing, but it’s funny anyway...A guy in a ‘not at all expensive’ suit asked a question to a brilliant nerd in a wooden box. The nerd in the box said, “...sorry, I’m a little nervous, this is my first time.” The guy in the ‘not at all expensive suit’ said, “...I don’t know if you’ve noticed, but this is my first time too”...And that’s not even the funny part. Later, the suit guy, stands up and says, “I’d like to record an objection, I’m not sure why, but it seems like there should be an objection here.” After the whole room stopped laughing, the nice old guy in the black dress said, “Then I’m go ahead and overrule that.” The room once again burst into laughter.”

¹⁵ Out of an abundance of caution Defense counsel did not request to be the foreman’s “friend” on Facebook. Id. Presumably, more posts may be visible to his “friends” on Facebook than to the general public.

Id. (emphasis added). The foreman's posts demonstrate that the government's strategy of using Dent and Johnson's wealth against them for an improper purpose worked.¹⁶ The foreman posted negatively about wealth in each post. Id. He found it humorous to watch a "rich guy" fall.

The pattern of emphasizing earnings pervaded the questioning of various witnesses as well. This emphasis on earnings confused the jury into believing that earnings from medical sales in general were somehow improper. For example, the government questioned Johnson about total earnings of BlueWave, even those that had nothing to do with a government payor. TT at 1393-94. The government further questioned Brad Johnson on his other business ventures that are not as financially successful as BlueWave, seemingly trying to imply that Johnson's success with BlueWave alone was an indication of illegality. TT at 1395:20 – 1396:6. The government compared BlueWave sales representative Boomer Cornwell's total commissions (again including those not related to Medicare or Tricare claims) with his earnings at other employers. TT at 378:14 – 20.

"Comments on the wealth of a party have repeatedly and unequivocally been held highly prejudicial, and often alone have warranted reversal." See, e.g., Hoffman v. Brandt, 65 Cal.2d 549, 55 Cal.Rptr. 417, 421 P.2d 425, 428 (1966) (reversal solely on improper reference, in closing, to party's pecuniary straits, and stating that "[j]ustice is to be accorded to rich and poor alike, and a deliberate attempt by counsel to appeal to social or economic prejudices of the jury,

¹⁶ Furthermore, because the foreman of the jury misrepresented to the Court and the parties his ability to follow the Court's instructions, Johnson and Dent have been severely prejudiced. Based upon the foreman's misconduct in not abiding by the Court's instructions to avoid posting on social media, there is no reason to believe that he followed any of the other Court's instructions. Surely he would have been struck for cause had he honestly answered the juror questionnaire and Court voir dire that he could not follow the Court's instructions. Given the high stakes of this case, such juror misconduct should not be countenanced nor ignored. Such misconduct negatively impacted both the defendants and the integrity of the court system, and mandates a new trial.

including the wealth or poverty of the litigants, is misconduct where the asserted wealth or poverty is not relevant to the issues of the case”); see generally [Jacob] Stein [Closing Arguments], supra at § 1:39 (Financial status of civil litigant).” Whittenburg v. Werner Enterprises Inc., 561 F.3d 1122 n.1 (10th Cir. 2009)(holding that plaintiff’s reference in closing argument to defendant’s wealth was improper and prejudicial). Evidence of a defendant’s net worth and wealth is “totally irrelevant to the issue of compensatory damages.” Burke v. Deere & Co., 6 F.3d 497, 513 (8th Cir. 1993); see also Draiper v. Airco, Inc., 580 F.2d 91, 95 (3d Cir. 1978) (granting a new trial in part because “[c]ounsel repeatedly made reference to the wealth of the defendants in contrast to the relative poverty of the plaintiff”). References to a party as a “wealthy, thriving, large company” and references to a company’s finances and size have been held irrelevant and excluded. Cooper Tire and Rubber Co. v. Farese, 2008 WL 5382416, at *3 (N.D. Miss. Dec. 19, 2008).

This case presents a unique example of how the Court’s decision to allow testimony of the defendants’ earnings and the government’s misuse of that evidence inflamed the jury in an improper way and led to a miscarriage of justice. The foreman of the jury found humor in watching the “rich” fall literally and financially. For this reason alone, this Court should set aside the verdict and order a new trial.

IX. The jury instructions as a whole misled the jury.

Courts have “considerable discretion in choosing the specific wording of [jury] instructions.” Figg v. Schroeder, 312 F.3d 625, 640 (4th Cir. 2002) (internal quotation marks omitted). But a verdict may be reversed for failure to “give an instruction proposed by a party only when the requested instruction (1) was correct; (2) was not substantially covered by the court’s charge to the jury; and (3) dealt with some point in the trial so important, that failure to

give the requested instruction seriously impaired that party's ability to make its case." Noel v. Artson, 641 F.3d 580, 586-87 (4th Cir. 2011) (internal quotation marks omitted). "The test of adequacy of instructions . . . is not one of technical accuracy in every detail." Spell v. McDaniel, 824 F.2d 1380, 1395 (4th Cir. 1987). Rather, it is a practical examination of "whether the instructions construed as a whole, and in light of the whole record, adequately informed the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party." Id.

The Court's instructions as a whole did not adequately inform the jury of the controlling law. First, the Court's instructions improperly combined two separate parts of the FCA. Dent and Johnson proposed two separate instructions for the government's two separate FCA claims. See Proposed Instructions at 14-15 [ECF No. 703]. The former instruction coincided with the first cause of action, a presentment claim (31 U.S.C. § 3729(a)(1)(A)), and the latter instruction applied to the second cause of action, a false statement claim (31 U.S.C. § 3729(a)(1)(B)). Id. Though the complaint even identifies these as separate claims, the Court's instruction combined the two claims into one instruction. TT at 2951-2955. At the outset, the Court is clear on the elements of the presentment claim, but as it goes on to instruct the jury on the second cause of action —the False Statement Cause of Action—it blends the instructions into one. Id. The Court never separates out the two claims under the FCA, which have distinct elements. The impact of such imprecision is that it widens the scope of liable conduct under the FCA. From the instructions, it is unclear what conduct specifically constitutes a violation of the FCA under False Statement theory. This opaqueness is sufficient to order a new trial.

Second, the Court instructed the jury on the wrong burdens of proof. Dent and Johnson proposed a clear and convincing burden of proof for the FCA claims. Prop. Instr. at 10. And it

proposed a beyond a reasonable doubt burden for the underlying AKS claim. Id. at 45. The Court, however, rejected both instructions and instructed that the government need only prove its case by a mere preponderance of the evidence, and the Court went on at length about the nature of this burden. Id. at 2944-45. Such standard is too low for proving violations of both statutes. First, the AKS is a criminal statute and criminal statutes require the government to prove its case beyond a reasonable doubt. Polk County v. Peters, 800 F. Supp. 1451, 1454 (E.D. Tex. 1992); Feldstein v. Nash Cnty. Health Serv., Inc., 51 F. Supp. 2d 673, 681 (E.D.N.C. 1999); United States v. Picciotti, 40 F. Supp. 2d 242, 248 (D.N.J. 1999).¹⁷ Second, because the penalty provisions of the FCA affect the constitutional rights and property interests of Johnson and Dent, fundamental due process requires the government to prove FCA fraud by clear and convincing evidence. Due Process Clause of the 5th and 14th Amendments; LaSalle, Frank (1995), “The Civil False Claims Act: The Need for a Heightened Burden of Proof as a Prerequisite for Forfeiture,” Akron Law Review, Vol.28: Iss. 3, Article 9 (available at <http://ideaexchange.uakron.edu/akronlawreview/vol28/iss3/9>); Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261, 285 n. 11 (1990). Because the Court improperly lowered the burden of proof for both the AKS and FCA, Dent and Johnson were prejudiced and this Court should order a new trial.

Third, the Court incorrectly instructed the jury it could make an adverse inference against Dent and Johnson from a third party’s invocation of the Fifth Amendment. Dent and Johnson

¹⁷ In re Winship, 397 U.S. 358, 364 (1970) (requiring beyond a reasonable doubt in a non-criminal proceeding); U.S. ex rel. Jamison v. McKesson Corp., 900 F.Supp.2d 683 n. 7 (N.D. Miss. 2012) (“the Court acknowledges that if this case were a closer call, the proper course would likely be to use criminal intent to prove a civil AKS violations.”); U.S. ex rel. Gonzalez v. Fresenius Medical Care N.A., 748 F. Supp. 2d 95, 113 (W.D. Tex. 2010); (failure to show AKS “criminal intent to induce referrals”); U.S. ex rel. Sharp v. Consolidated Med. Transp., Inc., No. 96-6502, 2001 WL 1035720, at *10 (N.D. Ill. Sept. 4, 2001) (FCA claim under the AKS “requires criminal intent”).

moved in limine to keep out any witness attempting to invoke the Fifth Amendment and opposed the government's motion for an adverse inference. [ECF No. 727, 736]. The court denied Dent and Johnson's motion. Id. In its instructions, the Court instructed the jury that it could infer that, if a witness pled the Fifth Amendment, the jury could infer that the answer would have been unfavorable to the witnesses' interests. TT at 2960-61. The Court then went on to state: "And if you find that such witness was a member of a conspiracy to violate the False Claims Act, you may but are not required to infer by such refusal that the witness's answer would have been unfavorable to the interests of any co-conspirator." TT at 2961:9-16. The Court committed significant error by inviting the jury to draw a negative inference against Dent and Johnson due to the invocation of the Fifth Amendment by a third-party because it failed to consider the necessary interests—outlined in its order on the government's motion in limine—before imputing an adverse interest against a third party. [ECF No. 736 at 18]; See LiButti v. United States, 107 F.3d 110, 123-24 (2d Cir. 1997). The Court's avoidance of this test through the use of "conspiracy" is significant legal error, and Dent and Johnson suffered significant prejudice because only a former BlueWave independent contractor invoked the Fifth Amendment. TT at 1045-63. But conspiracy was not submitted to the jury for a verdict. This Court should grant a new trial on this basis.

Fourth, the Court refused to charge the jury on materiality for the FCA claim. Dent and Johnson proposed a jury instruction that would require the jury to find a false claim or statement was material. Prop. Instr. at 14, 19. The Court did not charge the jury that it must find the false claim or statement material to the government's decision to pay. TT at 2946-51. A false claim under the FCA—even those claims relying on an underlying AKS violation—must be material to the payment decision; without such evidence, an FCA claim may not stand. Universal Health

Services, Inc. v. United States, 136 S.Ct. 1989, 2003–04 (2016); 31 U.S.C. § 3729(b)(4); City of Chicago v. Purdue Pharma, LP, 211 F.Supp.3d 1058 (N.D. Ill. 2016) (because claims were paid after lawsuit filed they were not material). Because the Court left out an element of the FCA offense for both the presentment and false statement claims, this Court should grant a new trial.

Fifth, the Court improperly limited the role of Dent and Johnson's good faith defense. Dent and Johnson proposed an instruction that properly noted that good faith can be a defense to both the AKS and the FCA. Prop. Instr. at 20. However, the Court limited its instruction on good faith only to the AKS: “A defendant who acts with a good-faith belief that his or her conduct is lawful does not willfully violate the [AKS] even if that belief is mistaken.” TT at 2951:6-8. The Court did not describe good faith as a defense to the FCA separately. The Court therefore limited Dent and Johnson's good faith defense to AKS violations, not all of the government's claims. This limitation misled the jury and created a situation where the jury could find that Dent and Johnson had a good faith defense to the AKS claims, but not to the separate FCA claims. Because the verdict form only mentioned FCA claims, the jury was not permitted to consider good faith as a defense to the actual claims on the verdict form. This is significant prejudice.

Sixth, the Court improperly disallowed Dent and Johnson to present a reliance on counsel defense. In February 2016, before any discovery in this case took place, the government sought and received prejudgment remedies against BlueWave, Dent, and Johnson. [ECF No. 178]. Dent and Johnson moved to quash. [ECF No. 277]. Dent and Johnson argued that the government could not prove its claims' “probable validity” because, inter alia, Dent and Johnson relied on counsel. Id. The Court rejected this argument. [ECF No. 310]. Dent and Johnson proposed this instruction; the Court did not allow it. Prop. Instr. at 21. The Court improperly disallowed Dent and Johnson from attempting to prove reliance on counsel. There was ample

testimony of the various attorneys that Dent and Johnson relied upon, from Gene Sellers to various attorneys present at the June 2013 “summit meeting.” See, e.g., TT at 1225-30 (describing who was at the summit meeting). The Jury should have been instructed that it could consider Dent and Johnson’s reliance on counsel as a defense. Depriving Dent and Johnson of a viable defense caused significant prejudice.

Finally, the Court misled the jury by refusing to instruct them on the trebling of damages or the implementation of penalties. The government moved to exclude any reference to trebling damages or statutory penalties. [ECF No. 736]. Dent and Johnson opposed such motion. [ECF No. 642]. The Court granted the motion and did not instruct the jury about the statutory damages or penalties. The jury then returned a verdict that constituted approximately 10% of the actual damages the government sought in this case. It is clear from the verdict that the jury did not believe Dent or Johnson should be held liable to the full extent the government sought. Said another way, the jury verdict went against 90% of the government’s claims. However, when statutory trebling and penalties are imposed, the jury’s 10% verdict (\$17 million) climbs to 15x the jury’s verdict (\$265 million) to 28x its verdict (\$475 million).¹⁸ This disparity deprives the jury of the right to impose partial liability because it completely negates their intent. Had the jury been fully informed, it would have in the province of the jury to award a partial verdict that, after trebling and penalties, equated to \$17 million. It deprives Dent and Johnson of their 7th Amendment right to jury determination; the jury is entitled to know the full impact of its verdict,

¹⁸ The statutory penalties should not be imposed or should be severely limited due to the 8th Amendment limitations. The Court previously noted that it would hesitate to enter any statutory penalties which would cause excessive punitive damages per the Supreme Court’s admonitions in BMW of North America, Inc. v. Gore, 116 S.Ct. 1589 (1996).

especially when it issues a compromise verdict. The prejudice is significant in light of the jury's overwhelming verdict in favor of BlueWave, Dent, and Johnson.

IX. The verdict is inconsistent.

The verdict is irreconcilably inconsistent because the jury found BlueWave not liable, and there is no way to find Dent and Johnson liable without finding BlueWave liable. The jury determined Dent, Johnson, and Mallory had committed FCA violations, but it vindicated BlueWave. [ECF No. 870]. But Dent and Johnson were the owners, officers, and representatives of BlueWave, and all acts taken to sell tests for HDL and Singulex were done through BlueWave. If BlueWave is not liable, there is no connection between Singulex or HDL and Dent and Johnson. Either all three were liable or none were. This material inconsistency shows the jury was fundamentally confused about the case. If BlueWave was not liable, then as a matter of law, Dent and Johnson cannot be liable. There is no reasonable or plausible explanation for the inconsistency and it results in a miscarriage of justice.

For these same reasons, the verdict was insufficient to support the jury's damages against Dent or Johnson. Johnson and Dent, acting through their own companies, were among those "salespeople" providing marketing materials. But Dent and Johnson would not have had personal involvement in every test referred to HDL or Singulex. To the contrary, Dent and Johnson would have had no involvement whatsoever in the vast majority of referred tests. Without finding BlueWave responsible or making a finding on the government's conspiracy claim, the verdict is insufficient to attribute damages to Dent and Johnson individually. Further, the government introduced no evidence of sales or damages attributable to Dent and Johnson for their individual marketing efforts. In other words, the government's claim for damages against Defendants Dent and Johnson for their own direct conduct would only involve false claims, if any, that they each

individually caused. At a minimum, a damages verdict must be supported by but-for causation.

United States v. Quicken Loans Inc., 239 F. Supp. 3d 1014, 1041 (E.D. Mich. 2017); see also United States v. Luce, 873 F.3d 999, 1013 (7th Cir. 2017); United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 491 (3d Cir. 2017); U.S. ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc., 597 F. Supp. 2d 1280, 1291 (M.D. Fla. 2009).

The verdict is irreparably inconsistent. And even if it can be construed as consistent, the verdict cannot support damages against Dent and Johnson because there is no evidence in the record that identifies the number of claims or total amounts attributable to Dent and Johnson for their own acts. For these reasons this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, grant a new trial.

X. Admission of uncommunicated work product led to a miscarriage of justice.

The verdict is a miscarriage of justice because the Court allowed the government to present uncommunicated work product as evidence of Dent and Johnson's scienter. In their discovery requests, the government sought attorney client communications from BlueWave, Dent, and Johnson. [ECF No. 410]. BlueWave, Dent, and Johnson refused and claimed privilege. Id. This Court ruled against BlueWave, Dent, and Johnson and went so far as to order them to produce "uncommunicated work product," a class of documents that, by definition, BlueWave, Dent, and Johnson had never seen. [ECF No. 410 at 8]. This decision allowed the government to introduce irrelevant evidence (it had previously disclaimed its interest in) to unfairly and improperly confuse the jury as it relates to Dent and Johnson's scienter; this misuse of evidence irreparably confused the jury and led to a miscarriage of justice.

The government's use of testimony and documents related to uncommunicated work product is especially egregious considering it made representations to a federal district court

judge in the Northern District of Alabama that it had no intention of seeking to use such documents because they would be irrelevant. After BlueWave, Dent, and Johnson claimed privilege over their attorney client communications and work product, in December 2016, the government took the unorthodox step to directly subpoena White, Arnold, and Dowd (“WAD”). WAD resides in Birmingham, Alabama. WAD sought to quash the subpoena and, eventually, counsel for BlueWave, Dent, and Johnson, WAD, and the government appeared in district court in Tuscaloosa, Alabama. At those hearings, the government repeatedly disclaimed a desire to review or to acquire uncommunicated work product.

At the first telephonic hearing on the subpoenas, the government attorney represented that the government did not seek anything beyond communications about the legality of the alleged conduct:

We agree that we are not entitled to anything beyond communications regarding the appropriateness or the legality of the alleged conduct. We are not looking to go beyond and to get into what, how [WAD] advised the Blue Wave Defendants on how to respond to the subpoena or how to answer various questions to the United States. . . . We are solely looking for communications regarding the appropriateness and legality of the conduct. . . . it would be limited to whether or not they provided advice or communications on that issue. And I think we would not try to go beyond that that would be sufficient for us.

February 8, 2017 Transcript at 11:15-25 – 12:1-13. (attached as Ex. C). The government attorney was clear to the court: “We are trying to limit this solely to communications regarding the legality or appropriateness of the ongoing conduct.” Id. 16:14-17.

At a second hearing, the government again reiterated its desire only to seek communications from WAD to BlueWave, Dent, or Johnson: “to the extent that [WAD] communicated with the BlueWave Defendants about the appropriateness or legality of the alleged conduct, the [P&H] Fees, the commission payments, and the zero balance billing, we are

entitled to that.” Feb. 22, 2017 Hearing Transcript 20:16-19 (attached as Ex. D)¹⁹. And in fact the agreement the parties provided on the record extended only to communications between WAD and the BlueWave Defendants. Id. at 45-55. The government did not seek anything beyond work product or attorney/client documents that were “communicated” to the clients because even the government realized that uncommunicated documents would be irrelevant to Johnson’s or Dent’s scienter. Regardless, the government did not update this Court of such change in position before it ruled on its pending motion to compel. [ECF No. 410].

Then, at trial, the government made most out of the (irrelevant) uncommunicated work product over Dent and Johnson’s objection. TT at 1217-1225. It used WAD attorney Linda Flippo to introduce a memo she wrote about the “summit” meeting on June 24, 2013. Govt Ex. 1034; TT at 1225. It contained Flippo’s mental impressions, legal strategy, and work product. Id. Because there were subpoenas pending, this memo was made in anticipation of litigation. There is no dispute that this memo was never produced to Dent or Johnson. In addition to this document, the Court allowed Flippo to testify about the meeting at length. TT at 1225-1240.

The introduction of uncommunicated work product is highly prejudicial and carries no probative value about Dent and Johnson’s state of mind; it cannot because they did not see it. Even the government recognized its irrelevance in the proceedings in Alabama. Yet, at trial, the government used the testimony and memo of attorney Flippo in an attempt to show Dent and Johnson’s scienter. Without a curative instruction, this testimony and document led to a miscarriage of justice.

XI. The government’s discovery abuse led to a miscarriage of justice.

¹⁹ A significant portion of this transcript occurred under seal. All such portions have been fully redacted here.

The government's discovery abuse—comprising “rolling production,” a delayed privilege log, and witness intimidation—led to a miscarriage of justice. At the outset of the case, the volume of documents promised to be significant and, therefore, the parties therefore agreed that a “rolling production” would be advantageous. To respond to the government's requests, Dent and Johnson hired a third party to process the documents and produced 357211 pages of material on June 13, 2016; 7,402 pages of material on June 16, 2016; 43,621 pages of material on June 22, 2016; 5,247 pages of material on July 19, 2016; 686 pages of material on November 17, 2016; and 241 pages of material on December 12, 2016.²⁰ This was well before the discovery cut off. In contrast, the United States produced 56 “rolling” responses from August 2017 through December 2017. See Production Chart (attached as Ex. E). The United States produced 2,944,513 pages of material during this time. The timing of the specific discovery responses greatly prejudiced Dent and Johnson.

For example, per the case scheduling order, and subsequent agreements by the parties, the expert reports of BlueWave experts Jennifer Bolen, Jessica Schmor, Curtis Udell, Dr. Robert Fishberg, and Daniel Mulholland were produced in January 2016. As contemplated by the scheduling order, the depositions of all these parties were completed by the end of May 2017. However, the United States' 50th, 51st, and 52nd productions, issued on October 6th, 2017, contain documents highly relevant to Dent and Johnson's expert's opinions.

First, United States production 50 contained information on CPT coding and the deposition transcript for Dr. Daniel Duvall taken in 2012 in the case of United States ex rel Strom v. Scios, Inc. and supporting exhibits dealing with CPT coding. From further review of

²⁰ These numbers do not include the additional attorney client materials produced in spring of 2017 (after this Court's order) or any discovery sought and produced under the Federal Debt Collection Procedure Act.

the materials, it appears that Dr. Duvall was involved in the decision-making process at DOJ in May 2014 in determining that Process and Handling Fees were allegedly bundled for payment within the Evaluation and Management Code. Dr. Duvall's knowledge and opinions provided to the United States are highly relevant to the defense as well as the BlueWave defendant's ability to adequately supply necessary information to coding experts for evaluation. Similarly, United States production 51 contains further information drafted by Dr. Duvall regarding CPT coding and his interpretation and opinion that all process and handling of blood samples is subsumed by the Evaluation and Management fee whether or not blood is actually drawn. This document was drafted on December 18, 2013 and was not produced until the 51st rolling production on October 11, 2017. Finally, United States production 52 again contained information on CPT codes and their application to process and handling of blood samples. As with productions 50 and 51, this information was highly relevant to BlueWave's defense as well as the opinions provided by BlueWave's experts on CPT coding and should have been provided to BlueWave long before October 2017 after close of discovery, Daubert motions, and first scheduled trial date.

All of this information would have been highly relevant to BlueWave's request for productions as well as necessary for review by its CPT coding experts, Jessica Schmor and Curtis Udell, in the preparation of their reports. Yet the United States chose to produce these documents (created well before any discovery requests went out) only after it has successfully excluded these experts from testifying in July 2017. This is an example of the government's misuse of the rolling production to deprive Dent and Johnson's expert of the information they needed to form their opinions.

On January 6, 2017, after several "rolling productions," BlueWave filed its first motion to compel and noted that it had not received yet received a privilege log. [ECF No. 350]. In

response, the United States was ordered to do so on April 27, regarding the 32 productions made as of that date. [ECF No. 428]. This was in spite of the fact that BlueWave had produced three separate privilege logs for its considerably smaller number of productions by that point in time. The government then provided two privilege logs: a twelve page log in May 2017 and then a 143 page log in August 2017. The government claimed and then immediately waived its “deliberative process” privilege over a vast swath of documents. By providing a complete privilege log months after discovery ended, the United States deliberately and effectively hid critical information for its defense.

Finally, the government turned over on August 8, 2017—at the time only three weeks before trial was scheduled—the Dennis Padgett report. Dennis Padgett is a CPT coding expert who provided a report to the United States in August 2014. That report directly contradicts the government’s legal position regarding the payment of process and handling through the evaluation and management code. It is inconceivable why the United States would choose to withhold this document until so late into its “rolling” production or at a minimum report the existence of Padgett’s report, but the import of its action is clear. BlueWave was deprived of its ability to provide this opinion to its own already excluded expert or to retain another expert to examine the opinion.

Therefore, counsel for BlueWave went directly to Mr. Padgett to determine if he still held the same opinion. When he confirmed that he did and was willing to testify by deposition, BlueWave then moved on October 20, 2017, to extend the scheduling order to allow for Padgett’s addition to the witness list. [ECF 691]. This motion was opposed by the United States [ECF 695], but was subsequently granted by the Court on November 2, 2017. [ECF 713].

Upon receiving the order, counsel for BlueWave immediately contacted Mr. Padget to coordinate the logistics of his deposition. Padget was subsequently contacted by attorneys for Berkeley Heart Lab requesting a conference call on the afternoon of November 6, 2017 with the government. This action along with Berkeley Heart Labs counsel's request that he destroy his supporting documents caused Mr. Padget substantial anxiety approaching intimidation against testifying. [ECF No. 720-1]. For this reason, Mr. Padget withdrew from testifying. In response to this strange turn of events, counsel for BlueWave filed a response to the United States' motion to exclude the testimony of Mr. Padget and also moved for sanctions.

Each of these vignettes in and of itself describes a disturbing discovery abuse. However, when put together, it is apparent Dent and Johnson were systematically deprived of the necessary discovery at the necessary time to do anything with it. For these reasons this Court should grant Dent and Johnson judgment as a matter of law or, in the alternative, the jury's verdict finding is against the clear weight of the evidence.

XII. The Court's exclusion of coding and legal experts led to a miscarriage of justice.

The court's exclusion of Dent and Johnson's coding and legal experts led to a miscarriage of justice because it deprived Dent and Johnson of helping the jury understand two key defenses in this case. First, the role of CPT code 99000 was a key issue to the verdict. As this Court charged the jury, there can be no "remuneration" under the AKS if a reimbursement did not constitute double payment and did not exceed fair market value. TT at 2949:23-24. The government introduced no evidence that the P&H Fees were above fair market value, and it provided only lay testimony that CPT code 99000 constituted double payment. TT at 549:18-21. Dent and Johnson proffered two experts who could provide expert testimony on this exact issue.

See [ECF No. 509, 527]. The government moved to exclude both, and the Court granted the motion. Id. The motion was granted after the discovery ended in this case.

Second, the ambiguity of the rules governing P&H Fees was a hotly contested issue in this case. A quick comparison of the opening and closing statements reveals a question of fact for the jury: whether there was a clear rule on P&H Fees and when that rule was established. To opine on this factual issue—whether the law was settled on this issue—Dent and Johnson proffered expert Dan Mulholland. [ECF No. 507]. Mr. Mulholland was prepared to testify that, at all times in question, the rules related to P&H Fees were unsettled. The government moved to exclude him, and the Court granted the motion. [ECF No. 507]. The Defendants' understanding—and, indeed, the possibility of their understanding—the labyrinthine rules and guidance on the differences between permissible reimbursements and illegal kickbacks (see, e.g., the list of factors set out in the June, 2014 Special Fraud Alert) was the central issue in this case. Mulholland's testimony would have been of great help to the jury. See United States v. Offill, 666 F.3d 168 (4th Cir. 2011); United States v. Barile, 286 F.3d 749 (4th Cir. 2002) (court should have considered admissibility of specific testimony of legal expert at trial rather than categorically exclude him).

These two exclusions require a new trial. First, it is clear from the discovery abuses discussed above neither Ms. Schmor, Mr. Udell nor Mr. Mulholland had everything the government had in its possession to render complete reports. Ms. Schmor and Mr. Udell did not have the benefit of Padgett's contrary 99000 analysis, and Mr. Mulholland did not have the benefit of Dr. Duvall's documents. These documents were produced after both experts were already excluded from the case. Second, the court erred in excluding both as fully detailed in the motions to reconsider both exclusions. [ECF Nos. 518, 525, 551]. Third, excluding all of Dent

and Johnson's experts—with the exception of Dr. Fishberg—deprived Dent and Johnson of an opportunity to contest significant issues in this case. Expert testimony is crucial on issues that go beyond the common experience of jurors; certainly coding and the ambiguity of P&H Fees fall outside of common experiences for jurors. By depriving Dent and Johnson of presenting explanatory or clarifying opinions on these two topics, deprived Dent and Johnson of any testimony on these subjects. This requires a judgment or a new trial.

XIII. Dent and Johnson are entitled to a set off.

Dent and Johnson are entitled to a set off. “[W]hen a plaintiff receives a settlement from one defendant, a nonsettling defendant is entitled to a credit of the settlement amount against any judgment obtained by the plaintiff against the nonsettling defendant as long as both the settlement and judgment represent common damages.” See Singer v. Olympia Brewing Co., 878 F.2d 596, 600 (2d Cir. 1989); Peterson v. Air Line Pilots Ass'n, 622 F. Supp. 232, 237 (M.D.N.C. 1985); accord Rutland v. South Carolina Dep't of Transp., 400 S.C. 209, 216, 734 S.E.2d 142, 145 (2012) (“[I]t is almost universally held that there can be only one satisfaction for an injury or wrong.”) (quotation marks and citation omitted). Settlement offsets are appropriate under the False Claims Act. See United States v. Zan Mach. Co., 803 F. Supp. 620, 623-24 (E.D.N.Y. 1992).

Further, the setoff should take place prior to any trebling of damages. The “norm” for set-offs and trebling is to apply any setoffs to the actual damages, and then treble the “net” damages that remain. United States v. Anchor Mortg. Corp., 711 F.3d 745, 749 (7th Cir. 2013). “The False Claims Act does not specify either a gross or a net trebling approach. Neither does it signal a departure from the norm—and the norm is net trebling.” Id. at 749. This is the majority position: See, e.g., id. (collecting cases).

Here, Dent and Johnson are entitled to setoffs from settling co-defendants and other parties that represent common damages. First, Dent and Johnson are entitled to a set-off of \$97,000,000 for HDL's settlement with the government. As explained in its proof of claim filed in the ongoing bankruptcy, HDL settled with the government for \$94,144,852.52. Proof of Claim (attached as Ex. F). The Settlement Agreement specifically references this lawsuit. Id. However, under the Settlement Agreement, HDL agreed to pay the government \$47,000,000.00 in fixed payments and certain contingency payments. Id. HDL's maximum amount of liability under the Settlement Agreement was capped at \$100,000,000.00. Id. As of the filing of the proof of service, HDL had paid some of its settlement. Id. The value of the settlement, therefore, is \$97,000,000.²¹ Second, the government settled with Singulex for \$1.5 million. Singulex Settlement (attached as Ex. G). Finally, it is unclear how much the government has recovered from physician practices that utilized HDL or Singulex tests. But any amounts attributable to such settlements must also be part of any set off. Thus, at a minimum, this Court should setoff \$98.5 million dollars from the jury's actual damages verdict against Dent and Johnson. In light of the uncertainty of total setoff, this Court should hold an evidentiary hearing to determine the proper amount of set off and, if necessary, allow post-trial discovery on this limited issue.

CONCLUSION

This is a unique case. The government conceded fair market value and seemingly lacked the evidence necessary to prove P&H Fees constituted remuneration. The foreman admitted on Facebook that he disdained the wealthy. Dent and Johnson are entitled to judgment as a matter of law or, in the alternative, a new trial.

²¹ It should be noted that the government compromised \$53,500,000.02 of its settlement in exchange for the estate's waiver of attorney client privilege. Motion to Allow Proof of Claim (attached as Ex. H). Because the government got value for the compromise, this is properly considered as value acquired under the settlement. Thus, the actual value of the HDL settlement for set-off purposes is \$97,000,000.

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Certificate of Service

I declare that I filed the foregoing on the court's electronic filing system, which forwarded an electronic copy to Plaintiffs' counsel.

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